

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In re: BAIR HUGGER FORCED AIR
WARMING PRODUCTS LIABILITY
LITIGATION

MDL No. 15-2666 (JNE/FLN)

This Document Relates To:
All Cases

**PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF MOTION TO
EXCLUDE OPINIONS AND TESTIMONY OF THOMAS KUEHN, PHD
PURSUANT TO FED. R. EVID. 702-703**

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Pursuant to Federal Rules of Evidence 702 and 703 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 570 (1993), Plaintiffs respectfully move this Court for an Order excluding the report and testimony of Defendants' proffered expert witness Thomas Kuehn, Ph.D., who disclosed expert opinions on issues of general causation. See Ex. A, Report of Thomas Kuehn ("Kuehn Rpt.").

Dr. Kuehn admitted he failed to employ any discernible methodology, repeatedly conceded his expert report was rife with errors, and therefore cannot meet Rule 702's reliability standards. While testing the parameters of an expert's opinions may generally be fodder for cross examination, when a technical expert attempts to offer an opinion which is utterly lacking in proper methodology, the Court has an obligation to exercise the gate-keeping function outlined by *Daubert*. Dr. Kuehn's opinions and testimony should be rejected as unreliable and of no assistance to the trier of fact.

I. INTRODUCTION

Although the Supreme Court has construed Rule 702 in favor of admitting expert testimony, there are limits. The proponent of the testimony, whether plaintiff or defendant, has the burden of establishing that the expert's testimony is based on a reliable methodology. Failure to show the reliability of each step in an expert's methodology is fatal under Rule 702 and *Daubert*.

Thomas Kuehn, Ph.D. ("Kuehn") is a mechanical engineer who, prior to his retirement, specialized in issues related to heat transfer. He is being offered by Defendants as an expert on filtration and airflow issues, and intends to offer partial

rebuttal to testimony offered by six of seven of Plaintiffs' experts: Dan Koenigshofer, PE, MSPH (HVAC); Said Elghobashi, M.Sc., Ph.D., D.Sc., (CFD); Michael Buck (particle testing on Bair Hugger); as well as Yadin David, M.D. (regulatory and design), William Jarvis, M.D. (infectious disease), and Michael Stonnington, M.D. (orthopedics).

Kuehn's opinions and testimony should be excluded for several reasons. Defendants cannot meet their burden of showing that Kuehn's testimony is reliable or relevant. Methodological errors and speculation permeate Kuehn's opinions at every step. His work in this case was largely limited to taking measurements of temperature and air velocity leaving the Bair Hugger, but at deposition he admitted to errors in measurement, errors in calculation, a lack of reproducibility and ultimately agreed that both his testing lacks methodology and that his experimental measurements are unreliable. Kuehn's proffered opinions lack basic hallmarks of reliability including: collecting measurements without confirming various key conditions in the testing environment; failing to control variables in his experiment; attempting to apply results from a faulty experiment to a completely different environment; and ignoring peer-reviewed literature that contradicts his opinion. Tellingly, Kuehn admitted that he failed to follow the kind of methodology he would expect even graduate students to employ outside the courtroom. Because his testimony is neither reliable nor helpful to the jury, it should be excluded.

II. FACTUAL BACKGROUND

On March 30, 2017, Plaintiffs disclosed the Rule 26 reports of seven experts on general causation issues, including Buck, David, Elghobashi, Koenigshofer, Jarvis and Stonnington. Ex.B, (Buck Rpt.); Ex. C (David Report), Ex. D (Elghobashi Report), Ex. E

(Koeningshofer Report); Ex. F (Jarvis Report); and Ex. G (Stonnington Report). These experts offer various opinions related to the Bair Hugger Forced Air Warming system (“Bair Hugger”), and ultimately conclude the Bair Hugger can cause deep joint infections (“DJI”) in exposed patients. Plaintiffs’ experts’ opinions are each based on relevant recognized methodologies, including comprehensive search of relevant literature, experiments, review of combination of numerous sources of evidence, internal 3M documents, and/or published peer-reviewed studies describing the mechanisms by which the Bair Hugger transmits particles and bacteria to the surgical site in hip and knee arthroplasties.

On June 1, Defendants disclosed the expert report of Thomas Kuehn, Ph.D., a mechanical engineer, to oppose plaintiffs’ expert opinions on filtration and airflow with respect to general causation issues. Ex. A. Unlike Elghobashi, Kuehn is not an expert in performing computational fluid dynamics. Unlike Jarvis and Stonnington, Kuehn has no professional experience in the hospital or surgical setting. Kuehn failed to perform a routine search of the relevant literature in developing his opinions. Ex. H, Deposition of Thomas Kuehn (“Kuehn Dep.”) at 93:11-94:15. Kuehn concedes he lacks expertise to opine on medicine, anesthesiology, infectious disease, orthopedics, microbiology, medical device design, medical device warnings, patient warming, operating room airflow, particle flow in an operating room, or how airborne particles cause PJI. *Id.* at 147:22-148:1; 151:14-16; 189:23-23; 190:1-3; 190:1-190:12; 193:22-24; 194:12-16; 288:10-23).

Based on his personal experiment in a room not representative of an operating room, Kuehn concluded that the Bair Hugger has a negligible effect on the airflow in an operating room. *Id.* at 179:23-180:7. Kuehn admitted in approaching problems as an engineer he would want to review and obtain as much peer-reviewed literature as is reasonably possible to see what others have done, but he failed to take the same approach in forming opinions he intends to offer inside the courtroom. *Id.* at 61:8-15. Kuehn failed to consider other sources of relevant medical evidence. Kuehn spent less than an hour conducting a search for the relevant medical and scientific literature, instead relying upon Defendants to provide relevant documents and articles. *Id.* at 61:14; 62:10. He considered only articles that 3M gave him with respect to the use of Bair Hugger and its effect on the operating room environment. *Id.* at 62:3-10. To his credit, Kuehn has admitted he failed to apply the same level of intellectual rigor in forming opinions he intends to offer in this Court that an expert in the relevant field would. For these reasons and others, as described in greater detail below, Plaintiffs respectfully submit this Court should exclude Dr. Kuehn from offering any testimony or opinions in this matter.

A. Kuehn Agrees With Plaintiffs' Experts On Many Key Facts And Principles

Dr. Kuehn agrees Plaintiffs and Plaintiffs' experts on many facts and principles.

- Kuehn agrees that particles under the operating table and/or on the floor of the operating room can be transported to the surgical site by use of the Bair Hugger. *Id.* at 324:5-12.
- Kuehn confirms bacteria can become aerosolized. *Id.* at 134:17-18.

- Kuehn agrees that physicians want to keep the sterile-field as particle-free as possible. *Id.* at 171:12-28.
- Kuehn agrees that if 3M was aware that Bair Hugger is associated with an increase in the number of particles over the surgical site, that is relevant information and 3M has an obligation to warn customers of that fact. *Id.* at 148:7-13.
- Kuehn believes in the validity of particle testing as an alternative to biological sampling. *Id.* at 89:15-90:6.
- Dr. Kuehn agrees particle counting can be appropriately used to measure the total (bacterial) aerosol concentration in an operating room (within the range of the instrument). *Id.* at 294:2-5.
- Kuehn agrees particle testing provides real-time data where biological sampling is delayed while the samples are sent for culturing. *Id.* at 90:19-91:9.
- Kuehn agrees use of neutrally buoyant helium bubbles, such as those used in both the McGovern and Belani studies, is a reasonable methodology. *Id.* at 319:8-15.
- Kuehn has used neutrally buoyant bubbles himself. *Id.* at 319:5-7.
- Kuehn agrees that calling a filter a “[0].2 micron high efficiency filter” does not provide any quantitative information about the filter. *Id.* at 144:5-21.

- Kuehn agrees that the air underneath the operating table has a greater concentration of bioburden than other areas in the operating room. *Id.* at 182:15-24.
- Kuehn agrees turbulence will affect particle movement. *Id.* at 197:7.
- Kuehn agrees Schelerin testing is not widely used by engineers in his field. *Id.* at 84:11-25.
- Kuehn agrees that the boussinesq approach to CFD is the wrong approach to predicting particle flow when there are large temperature gradients, which impact both density and viscosity. *Id.* at 53:23-54:2.
- Kuehn agrees that Bair Hugger uses power to create heat, and that the Bair Hugger is the most energy intensive piece of equipment in the operating room. *Id.* at 208:22-209:6.
- Kuehn is unaware of any other device in the operating room that produces more watts of heat around the patient than the Bair Hugger does. *Id.* at 209:10-13.
- Kuehn agrees that the Bair Hugger may cause particles to travel from the floor to the surgical site. *Id.* at 323:5.

Kuehn agrees that particles will travel from the blower to the blanket, that some of these particles will leave the blanket, and that some of the particles that leave the blanket will contain bacteria. *Id.* at 327:23.

1. Kuehn Agrees Elghobashi Is An Expert

At his deposition, Kuehn agreed Elghobashi is an expert in particle movement (Kuehn Dep. p. 199:1-3), and agreed that Elghobashi did both the equations and calculations included in his report correctly. *Id.* at 260:13-21. Kuehn takes issues with just two assumptions Elghobashi made with respect to his CFD model: the temperature leaving the Bair Hugger blanket and the number of particles Elghobashi placed near the floor for his model. *Id.* at 260:22-261:19. Kuehn disputed the temperature Elghobashi used in his CFD model because it conflicted with the temperature Kuehn measured in his attempted experiment. *Id.* at 260:22-261:2. But at deposition Kuehn admitted the temperature measurements he took were unreliable and inaccurate. *Id.* at 243:12-15. The temperature assumption Elghobashi used originated from 3M documents with respect to temperature of air leaving the Bair Hugger blanket. Ex. D. The number of particles placed into Elghobashi's CFD model was three million, a small percentage of the ASHRAE estimate of 100 to 900 million squames shed during a typical surgery.

2. Kuehn Agrees Particle Counting is Valid Methodology

Next, Kuehn turns to Michael Buck's report. Kuehn is critical of the logarithmic scale Buck used in his report, and the lack of clarity with respect to what exact conditions were being tested at each time scale. Ex. A at 14. Kuehn criticizes Buck for not replicating his tests a minimum of three times for each condition to ensure statistical accuracy, (*id.*), but when it came to his own experiment Kuehn failed to take measurements at least three times, and admits he did not do a statistical analysis to see if the values he obtained were statistically significant or not. Kuehn Dep. 131:1-4. Finally,

Kuehn notes that Buck could have done bacterial sampling in order to measure the nature of the particles. But what Buck “could have done” or “should have done” is meaningful only in the context of Buck’s proposed testimony. Buck did not offer any opinion on the nature of the particles, so Kuehn’s criticism is misplaced.

3. Kuehn Admits Particles Containing Bacteria Exit Through Holes in Bair Hugger Blanket

Finally, Kuehn’s sole criticism of Dr. David, Dr. Jarvis, and Dr. Stonnington relates their respective citations to the Tsai et. al.¹ study, which studied an electrical malfunction within a Bair Hugger that generated soot which traveled through the Bair Hugger system and through the Bair Hugger blanket to deposit the black soot on the patient and surrounding blankets.

Kuehn agreed the black soot documented the photographs from the Tsai study appears to be deposited near the location of the holes in the Bair Hugger blanket. Ex. A, Kuehn Rpt. 15. Tsai et. al. presented the findings at a professional conference. Kuehn doesn’t dispute Tsai et. al.’s findings, but disagrees that the passage of soot particles through the Bair Hugger blanket provides evidence that pathogens can pass through the Bair Hugger system. *Id.* Kuehn’s disagreement with David, Jarvis, and Stonnington’s citation to the Tsai article seems to be because soot particles aren’t the same as other particles, not because he thinks potentially infectious pathogens don’t travel through the Bair Hugger filter, blower, hose, and blanket. During his deposition, Kuehn agreed that particles travel from the Bair Hugger blower to the blanket, that some of these particles

¹ J Tsai et al., *Forced Air Warming Device Failure Resulting in Smoke and Soot on a Surgical Patient*, 4 OPEN ACCESS JOURNAL OF SURGERY (2017)

leave through the holes in the blanket, and that some of those particles will contain bacteria. Kuehn Dep. 327:23-328:3. To the extent Kuehn is critical of Plaintiffs' experts', it seems to be a criticism of form over foundation.

III. LEGAL STANDARDS

Federal Rule of Evidence 702 permits expert witnesses to testify if the subject of their testimony is relevant, the witnesses are qualified to express their opinions, and the proposed evidence upon which they base their testimony is reliable or trustworthy. *Polski v. Quigley Corp.*, 538 F.3d 836, 839 (8th Cir. 2008).

Courts are the gatekeeper of evidence proffered under Rule 702, "to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999).

Expert testimony must be trustworthy for it to be reliable. *Daubert*, 509 U.S. at 590. That is, the testimony must be supported by appropriate validation. *Id.* Four nonexclusive factors control the reliability of expert testimony: "(1) whether the theory or technique can be and has been tested; (2) whether the technique has been subject to peer review and publication; (3) the technique's known or potential rate of error; and (4) the level of the theory or technique's acceptance within the relevant discipline." *Id.* at 593-94.

The Eighth Circuit considers additional factors as well, including: "whether the expertise was developed for litigation or naturally flowed from the expert's research;

whether the proposed expert ruled out other alternative explanations; and whether the proposed expert sufficiently connected the proposed testimony with the facts of the case. *Polski*, 538 F.3d at 839. The party seeking admission of expert testimony has the burden of demonstrating its reliability. *In re Baycol Prods. Litig.*, 532 F. Supp. 2d 1029, 1042 (D. Minn. 2007).

A “very significant” criterion for reliability is whether the expert’s testimony is based on research independent of litigation. *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995) (Daubert II). “If the proffered expert testimony is not based on independent research, the party proffering it must come forward with other objective, verifiable evidence and explain precisely how they went about reaching their conclusions and point to some objective source—a learned treatise, the policy statement of a professional association, a published article in a reputable scientific journal or the like—to show that they have followed the scientific method, as it is practiced by (at least) a recognized minority of scientists in their field.” *Id.*, 43 F.3d at 1317-19.

Expert testimony that “rests upon ‘good grounds, based on what is known’ [...] should be tested by the adversary process with competing expert testimony and cross-examination, rather than excluded by the court at the outset.” *Johnson v. Mead Johnson Co.*, 754 F.3d 557, 562 (8th Cir. 2014)(quoting *Daubert*, 509 U.S. at 590, 596)). Where the factual basis, data, or the methodology employed by the expert are sufficiently called into question, the court must determine not only if the testimony is reliable, but also whether it has a valid connection to the pertinent inquiry. *Kumho Tire*, 526 U.S. 137 at 149; *see also* Rule 702. Expert testimony must therefore “logically advance[] a material

aspect of the proposing party's case." *Daubert*, 509 U.S. at 597. The court should not admit opinion evidence "that is connected to existing data only by the *ipse dixit* of the expert," *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 157 (1997), or that is based on an expert's own unique methodology rather than a respected methodology. *Groobert v. President and Directors of Georgetown College*, 219 F. Supp. 2d 1 (D.D.C. 2002). Under these circumstances, a court may conclude there is simply too great an analytical gap between the data and the opinion." *Gen. Elec. Co. v. Joiner*, 522 U.S. at 146. Because Kuehn's opinions are fundamentally unsupported, they must be excluded.

IV. ARGUMENT

Dr. Kuehn claims to render the following opinions:

1. Bair Hugger filters are effective at removing airborne bacteria from the air that passes through them.
2. Bair Hugger filters are appropriate for use in the operating room.
3. HEPA filtration is unnecessary for effective control of bacteria in air.
4. M20 filters meet the requirements for MERV 14.
5. The change from M10 to M20 media should not have made any difference in the Bair Hugger filter's capture of harmful pathogens.
6. Using the maximum air velocity that was measured and published literature on particle motion and removal from surfaces, Plaintiffs' experts are wrong to conclude the Bair Hugger can remove particles from the floor.
7. It is unlikely surgeons would notice any difference in temperature or any change in airflow as a result of temperature, when Bair Hugger is on.

8. While Bair Hugger may be the most energy intensive piece of equipment in the OR, equipment thermal load is not a very important portion of cooling load in an OR.
9. The temperature of the air leaving the Bair Hugger blanket is 75°F, not 106°F. Thus, the assumed thermal buoyancy of the warm air leaving the blanket is incorrect.
10. Rather than do a CFD study with three million particles, perhaps Elghobashi could have used ten million or one hundred million particles. Alternatively, Elghobashi could have modeled an estimated number of culturable particles.

He then claims the following conclusions:

1. Room ventilation is not significantly affected when the Bair Hugger is operated.
2. The air velocity near the floor generated by the Bair Hugger is insignificant compared to the air velocity driven by the ventilation in the room, movement of personnel and the operation of other equipment.
3. Air velocity in a simulated OR configuration did not show any measurable difference when the Bair Hugger was turned off or turned on at high speed.
4. When the Bair Hugger is used with the cart, the air velocity near the floor under the unit is insignificant.
5. The temperature of the air leaving the blanket will not have a significant effect on the movement of the warm air leaving the blanket.

6. It is very unlikely that any infectious particles residing near the floor in any of the areas simulated will ever reach the critical care area.
7. The particle movement simulation results will not cause any significant contamination of the critical care area from particles located near the floor.

None of these opinions and conclusions, however, are supported by any special expertise that Kuehn has, nor are they supported by any scientific methodology. Indeed, several of the opinions Kuehn includes in his written report are inconsistent with testimony he provided at deposition. Because they are unreliable and unsupported, Kuehn's opinions should be excluded at trial.

A. Kuehn Disclaims Expertise In Many Key Areas

In addition to the limitations with respect to foundation Dr. Kuehn lacks with respect to issues touching on engineering, Dr. Kuehn disclaims expertise in at least:

- Not an expert in surgery or orthopedics (Kuehn Dep. 147:22-148:1);
- Not an expert in infectious disease issues, (*Id.* at 151:14-16);
- Not an expert in medicine (*Id.* at 189:23-25);
- Not an expert in peri-prosthetic joint infection ("PJI"), or how many colony forming units may be required to cause a PJI (*Id.* at 190:4-8);
- Not an expert in manufacturing filters (*Id.* at 190:20-22);
- Not an expert in medical device design (*Id.* at 190:23-25);
- Not an expert in medical device warnings (*Id.* at 191:1-4);
- Not an expert in anesthesiology (*Id.* at 191:5-7);
- Not an expert in patient warming issues (*Id.* at 191:8-12);

- Not an expert in airflow in an operating room (*Id.* at 193:22-24);
- Not an expert in particle flow in an operating room (*Id.* at 194:12-16);
- Not an expert in how skin squames are transported in an operating room (*Id.* at 252:11-14);
- Not an expert in microbiology (*Id.* at 288:10-18).

Having disclaimed any expertise in these areas, Kuehn should be excluded from testifying on any topics that would require this expertise.

For example, Kuehn's report says, based on his unreliable measurements, that Bair Hugger would not impact air flow in the OR. But to make that statement Kuehn would have to apply his measurements to the airflow in the OR. Kuehn cannot do that because he concedes he is not an expert in OR airflow. *Id.* at 193.22-24. And he did not perform CFD or any other calculations to simulate the impact of Bair Hugger on those airflows. Kuehn Report. He simply concludes, without support, that Bair Hugger has no impact.

B. Kuehn Had Insufficient Information to Offer Expert Opinions

One of the perils of acting as a litigation expert is relying on information spoon-fed by counsel. *In re TMI Litig.*, 193 F.3d 613, 698 (3d Cir. 1999). Kuehn did not conduct appropriate independent research; instead, he considered only the handful of articles and documents 3M provided him. *Id.* at at 62:10. Among those documents were two deposition transcripts and three internal documents related to purported filter testing done in 2016, together with thirteen articles, only three of which touched on Bair Hugger specifically. Ex. C (Exhibit E to the Kuehn Rpt).

Kuehn admitted his normal practice would be to, as much as is reasonably possible, obtain and review all the relevant literature on that issue to see what other people have done. *Id.* at 61:8-12. In approaching this case, however, Kuehn concedes his independent research wasn't exhaustive: he did an internet search that lasted less than an hour, and otherwise relied on Defendants to provide him with all documents relevant to his report. *Id.* at 61:14-18. His unexplained departure from his normal, academic practice outside the courtroom reflects litigation bias, not sound science. Several courts have cautioned that an expert's opinion is unreliable if the expert fails to acknowledge or account for relevant scientific literature that tends to refute the expert's theory. *See Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 519 (S.D.W. Va. 2014) (collecting cases). Kuehn had no reliable basis to read and consider only the handful of studies provided to him by 3M. That alone should be a basis to exclude his testimony.

Kuehn conceded he did not have all the information he would need to render his opinions in this matter. By way of example, Kuehn agreed that if all peer-reviewed literature and internal testing indicate that particles increase over the surgical site when the Bair Hugger is turned on, that would be relevant information for him to know in forming his opinions in this case. Kuehn Dep. 88:22-89:8. But 3M failed to provide Kuehn with the key articles discussed by nearly all the experts in this case: the Legg studies, Desari paper, Sessler, Huang, Morretti, Brandt, and McGovern studies. *Id.* at 125:8-126:11. Nor did 3M provide Kuehn with any internal emails or internal testing. *Id.* at 127:14; 92.

C. Kuehn Failed to Follow Recognized Scientific Methodology In Conducting His Experiment and Concedes Unreliable Results

In addition to offering opinions on matters outside of his area of expertise, Kuehn offers opinions on testing he performed during the course of this litigation. Kuehn admitted the testing was unreliable and that he did not disclose any methodology. As such, the testing should be excluded.

1. Kuehn Admits Lack Of Methodology

At his deposition, Kuehn admitted his opinion that the Bair Hugger has a “negligible effect on airflow in an operating room” is based solely on the measurements he took regarding the velocity of the air leaving the blanket, as documented on Exhibit B to his report. *Id.* at 179:23-180:3.

Kuehn admits this opinion is based exclusively on the measurements he took in a room set up by 3M (*id.* at 210:2), where the room configuration was not that of a typical operating room (*id.* at 226:6-7), and which lacked both surgical lights (*id.* at 226:8) and operating room staff such as surgeons and anesthesiologists. *Id.* at 226:11. These omissions despite Kuehn’s recognition that surgeons and other OR staff will affect the airflow, turbulence, and heat transfer in an operating room. *Id.* at 226:14.

Kuehn admits he changed the room thermostat during his experiment, but he not recall where the temperature was initially set, or what temperature he turned the thermostat up to. *Id.* at 226:23-227:13. Kuehn concedes this temperature change impacts whether or not the room reached equilibrium prior to the experiment, and confesses the

fact that the room may not have been in equilibrium is another variable he failed to account for in reaching his conclusions. *Id.* at 227:12-228:19.

Kuehn is prepared to offer his opinion to the jury, despite the fact it lacks reliability and cannot be reproduced. *Id.* at 237:13. Kuehn is consciously unaware of key peer-reviewed publications that reach the opposite conclusion, and he simply dismissed the few studies he was made aware of that contradict his opinion. He does not describe, much less cite, an objectively verifiable source for his conclusion that the Bair Hugger has no meaningful impact on airflow in an operating room, and he intends to offer that conclusion despite explicitly disclaiming expertise in operating room airflow. *Id.* at 193:22-24.

Kuehn's testimony must be excluded because even Dr. Kuehn agreed it lacks methodology. Dr. Kuehn confirmed over and over there is no methodology in his report:

Q: Well I mean part of writing a scientific report is that someone else could reproduce the results, correct?

A: Yes

Q: Okay. None of that is in this report; correct?

A: Without additional information, that's correct.

Q: I'm asking you in this report is there any - - Is there a methodology written out in this report how this was done?

A: No, there's no methodology.

Q: There's no methodology in this report, is there?

A: No.

Kuehn Dep. 237:13-238:3.

Q: I mean would you accept a report like this from one of your students doing a thesis for a Ph.D.?

A: Not solely, no.

Q: I mean you'd expect some sort of methodology and some way to determine that the data is reliable; correct? Correct?

A: Yes.

Q: Okay. There's definitely no methodology here that's indicated in this report; correct?

A: Yes.

Q: And as of right now, the reliability is very questionable; correct?

[Counsel for Defendants]: Objection to form, asked and answered.

A: I would – I would say reproducing the results here would – would be difficult.

Kuehn Dep. 249:17-250:9.

Q: Exhibit B of your report, there's no methodology, can't be reproducible, therefore it's not reliable, correct?

[Counsel for Defendants]: Objection to form, asked and answered.

A: If – if that's how you define 'reliable', I will agree with that.

Q: Well how do you define "reliable"?

A: I think I would say something that – that could be reproduced.

Q: We can't reproduce this; can we?

A: Not with what's here, no.

Q: Okay. So therefore this report, based on what's here, is not reliable.

[Counsel for Defendants]: Objection to form.

A: By inference, yes, I agree.

Keuhn Dep. 251:17-252:6.

Testability is one of the recognized indicators of whether the expert's theory of causation is reliable under Rule 702. *Daubert*, 509 U.S. at 593. This method consists of repeating the experiment to determine whether it produces the same result. But here Kuehn concedes his experiment cannot be reproduced. No matter which expert is offering it, an opinion based on unsupported speculation is unreliable. *See Glastetter v. Novartis*, 107 F. Supp. 2d 1015, 1045 (E.D. Mo. 2000).

2. Kuehn's Experiment is Unreliable

Dr. Kuehn simply assumed, without any corroboration, that the data he measured in a room at Defendants' headquarters was an appropriate environment to conduct a study, despite recognizing the room did not approximate the configuration of an operating room. This unsupported assumption alone destroys the reliability of Kuehn's conclusions about the impact of a Bair Hugger on airflows in an operating room, particularly when coupled with his disclaimer of any expertise in airflow in an operating room. An expert's reliance on unfounded assumptions in comparative analysis creates "too great an analytical gap" between his opinion and the data on which it relies. *Junk v. Terminix Intern. Co.*, 628 F.3d 439, 448 (8th Cir. 2010). Kuehn's analysis is therefore unreliable and should be excluded.

In sum, Kuehn's report rests on untestable assumptions. Good scientists would independently verify that the underlying data is accurate and complete before attempting to analyze it. Kuehn did not do so, nor did he consider the great weight of peer-reviewed publications and testimony in this litigation contradicting his opinion. Kuehn disqualified himself by agreeing he is not an expert in airflow in an operating room. Kuehn Dep.

193:22-24. Because Defendants have failed to show by a preponderance of evidence that Dr. Kuehn's methods are reliable, his opinion testimony should be excluded under Rule 702. *In re Baycol Prods. Litig.*, 532 F. Supp. 2d at 1042.

For all these reasons, Kuehn's conclusions are flawed and tainted by litigation bias. *See Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 40 (2011). *See also Sorensen v. Shaklee Corp.*, 31 F.3d 638, 649 (8th Cir. 1994)(disavowing expert's backward reasoning to achieve desired conclusion). Indeed, Kuehn's "unique methodology," generated from litigation – one which he admits he would not accept from a Ph.D. student - is not a recognized approach to engineering problems. *See Groobert*, 219 F. Supp. 2d at 9. His opinions should therefore be excluded.

Dr. Kuehn's testimony on general causation analysis fails under Rule 702 because he did not follow the generally accepted methodology for determining whether the association between the Bair Hugger device and DJI was a causal one. His opinion on this issue is not only unreliable; it is also irrelevant and unhelpful to the jury.

Kuehn did not perform any meaningful independent investigation or consider other relevant literature; he concedes he relied exclusively on the handful of documents supplied by 3M. Kuehn Dep. 62:10. And yet Kuehn intends to offer expert testimony in this case as to the ultimate issue: whether the Bair Hugger disrupts the airflow in an operating room, causing bacteria-laden particles to travel to the surgical site.

In making causation judgments, it is important to evaluate data relevant to the mechanism of injury. Assessing the biological plausibility of an association "depends upon existing knowledge about the mechanisms by which the disease develops." *See*

Michael D. Green, D. Michal Freedman, & Leon Gordis, *Reference Guide on Epidemiology*, in *Reference Manual on Scientific Evidence* 549, 604-605 (Federal Judicial Center, 3d ed. 2011). When such evidence exists, “it lends credence to an inference of causality.” *Id.*

Dr. Kuehn is an engineer. His unwillingness to even consider the relevant mechanical or biological data disqualifies him from being allowed to address causation. His failure to consider the relevant peer-reviewed literature, including biological data on the Bair Hugger’s mechanisms for causation create “too great an analytical gap” between his opinion and the limited data he relies upon. *Gen. Elec. Co.*, 522 U.S. at 146.

The lack of foundation for Dr. Kuehn’s general causation opinion also undercuts its relevance. His opinion testimony simply does not advance the jury’s understanding of whether the Bair Hugger impacts airflow in an operating room. Because such expert testimony is both powerful and misleading, it is therefore unduly prejudicial. *Daubert*, 509 U.S. at 595. The Court should also exclude Dr. Kuehn’s general causation opinion.

V. CONCLUSION

For the reasons stated above, Plaintiffs ask the Court to Exclude the Testimony of Thomas Kuehn, Ph.D.

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